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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,383	07/09/2003	Timothy J. Foster	P06335US03/BAS	5842

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EXAMINER	
ARCHIE, NINA	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/615,383	FOSTER ET AL.	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/20/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Drawings

2. The drawings in this application have been accepted. No further action by Applicant is required.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because: Non-initialed and or non-dated alteration has been made to the oath or declaration. See 37 CFR 1.52 (c).

Information Disclosure Statement

4. The information disclosure statement filed on 1/20/2004 has been considered. An initialed copy is enclosed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-2, 4-5, 8-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 8, 11-13 of U.S. Application No. 10,378,674.

In the instant case, the claims are drawn to independent claims, an isolated antibody that binds to the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis (claim 1); an isolated antibody that is reactive with the ligand binding A region of the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis (claim 8); a diagnostic kit comprising antibodies reactive with an SdrG protein from coagulase-negative Staphylococcus epidermidis which is cell-wall associated and which binds both soluble and immobilized fibrinogen (claim 11);

Claims 1-6, 8,11-13 of U.S. Application No. 10,378,674 teach an antibody that binds to the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis, wherein the protein is cell-wall associated, and binds both soluble and immobilized fibrinogen, which is raised against the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis, which is raised against the A region of the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis, isolated antisera containing the antibody of claim 1, an isolated antibody that is reactive with the ligand binding A region of the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis, a diagnostic kit comprising the antibody according to Claim 1 and a means for identifying binding by said antibody.

Although the conflicting claims are not identical, they are not patentably distinct. The U.S. Application No. 10,378,674 recites the "monoclonal antibody". The species of the monoclonal antibody anticipate the genus claims of any antibody.

Thus, claims 1-2, 4-5, 8-11 encompassing the antibody in the present application are obvious over claims 1-6, 8,11-13 of U.S. Application No. 10,378,674.

6. Claims 1-8, 10 and 13-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14, 16-17 and 23 of U.S. Application No. 10,690,184.

In the instant case, the claims are drawn to independent claims, an isolated antibody that binds to the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis (claim 1); an isolated antibody that is reactive with the ligand binding A region of the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis (claim 8); an isolated antibody reactive with a protein that is cell wall- associated, exhibits cation-dependent ligand-binding and has a highly conserved motif of which the consensus sequence is TYTFTDYVD (SEQ ID NO: 16), wherein the protein is isolated from coagulase-negative Staphylococcus epidermidis (claim 13).

Claims 14, 16-17 and 23 of U.S. Application No. 10,690,184 teach an antibody that binds to the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis, wherein the protein is cell-wall associated, and binds both soluble and immobilized fibrinogen, wherein the antibody recognizes a protein that is cell wall-associated, exhibits cation-dependent ligand-binding and has a highly conserved motif of which the consensus sequence is TYTFTDYVD (SEQ ID NO: 16), which is raised against the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis, which is raised against the A region of the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis, wherein the SdrG fibrinogen-binding protein comprises SEQ ID NO:10, wherein the

SdrG fibrinogen-binding protein is encoded by the nucleic acid comprising SEQ ID NO:7, isolated antisera containing the antibody according to claim 1. Furthermore U.S. Application No. 10,690,184 teach an isolated antibody that is reactive with the ligand binding A region of the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis, an isolated antibody reactive with a protein that is cell wall-associated, exhibits cation-dependent ligand-binding and has a highly conserved motif of which the consensus sequence is TYTFTDYVD (SEQ ID NO: 16), wherein the protein is isolated from coagulase-negative Staphylococcus epidermidis.

Although the conflicting claims are not identical, they are not patentably distinct. The U.S. Application No. 10,690,184 recites the "antibody". The species of the monoclonal antibody anticipate the genus claims of any antibody.

Thus, claims 1-8, 10 and 13-15 encompassing the antibody in the present application are obvious over claims 14, 16-17 and 23 of U.S. Application No. 10,690,184.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application

filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1-5, 8-10, and 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Guss et al WO 97/48727.

The claims are drawn to an isolated antibody that binds to the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis (claim 1); an isolated antibody that is reactive with the ligand binding A region of the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis (claim 8); a diagnostic kit comprising antibodies reactive with an SdrG protein from coagulase-negative Staphylococcus epidermidis which is cell- wall associated and which binds both soluble and immobilized fibrinogen (claim 11); an isolated antibody reactive with a protein that is cell wall- associated, exhibits cation-dependent ligand-binding and has a highly conserved motif of which the consensus sequence is TYTFTDYVD (SEQ ID NO: 16), wherein the protein is isolated from coagulase-negative Staphylococcus epidermidis (claim 13).

Guss et al teach a fibrinogen binding protein originating from coagulase-negative staphylococci (see abstract). Guss et al teach a nucleic molecule and encoded protein form S. epidermidis where the protein contains a conserved TYTFTDYVD sequence where the nucleic acid molecule encodes the protein and has about 95% homology to SEQ ID NO: 7 (see Figure 6, and STIC RESULTS). Guss et al teach antibodies against the SdrG fibrinogen-binding protein (see pg. 4 last paragraph, Example 1, Example 5). Guss et al teach a diagnostic kit for determining the presence comprising a fibrinogen binding protein originating from coagulase-negative staphylococci (see abstract). Therefore Guss et al anticipate an isolated antibody that binds to the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis. Guss et al inherently teach that the protein is cell-wall associated, and binds both soluble and immobilized fibrinogen. Therefore the antibodies of Guss et al recognizes a protein that is cell wall-associated, exhibits cation-dependent ligand-binding and has a highly conserved motif of which the consensus sequence is TYTFTDYVD (SEQ ID NO: 16). Therefore Guss et al anticipate that an isolated antibody is raised against the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis, raised against the A region of the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis. Guss et al teach that region called A (see Figure 7) of the of the FIG protein (fibrinogen SdrG binding protein) therefore Guss et al anticipate an isolated antibody that is reactive with the ligand binding A region of the SdrG fibrinogen-binding protein from coagulase-negative. Guss et al each isolated antisera containing an antibody (see figure 11). Guss et al teach the consensus sequence is TYTFTDYVD (SEQ ID NO: 16) and antibodies against the protein comprising the sequence thus Guss et al anticipate an isolated antibody reactive with a protein that is cell wall-associated, exhibits cation-dependent ligand-binding and has a highly conserved motif of which the consensus is consensus sequence is TYTFTDYVD (SEQ ID NO: 16), wherein the protein is isolated from coagulase-negative Staphylococcus epidermidis (see Figure 6, and STIC RESULTS), wherein the protein comprises SdrG fibrinogen-binding protein isolated from coagulase-negative Staphylococcus epidermidis, wherein the protein comprises the ligand binding A region of SdrG fibrinogen-binding protein isolated from

coagulase-negative Staphylococcus epidermidis (see abstract, pg. 4 last paragraph, Example 1, Example 5, Figure 6 and Figure 7).

As to dependent claim 9 and independent claims 11-12, a diagnostic kit comprising the antibody according to Claim 1 and means for identifying binding by said antibody (claim 9); a diagnostic kit comprising antibodies reactive with an SdrG protein from coagulase-negative Staphylococcus epidermidis which is cell-wall associated and which binds both soluble and immobilized fibrinogen (claim 11); a diagnostic kit comprising antibodies reactive with a protein that is cell-wall associated, exhibits cation-dependent ligand-binding and has a highly conserved motif of which the consensus sequence is TYTFTDYVD (SEQ ID NO: 16), wherein the protein is isolated form coagulase-negative Staphylococcus epidermidis (claim 12); A kit is defined as a set or collection of articles used together therefore Guss et al anticipate a diagnostic kit.

8. Claims 1-6 and 8-15 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,380,370 Doucette-Stamm et al Date April 30, 2002 (US Filing Date August 13, 1998).

The claims are drawn to an isolated antibody that binds to the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis (claim 1); an isolated antibody that is reactive with the ligand binding A region of the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis (claim 8); a diagnostic kit comprising antibodies reactive with an SdrG protein from coagulase-negative Staphylococcus epidermidis which is cell- wall associated and which binds both soluble and immobilized fibrinogen (claim 11); an isolated antibody reactive with a protein that is cell wall- associated, exhibits cation-dependent ligand-binding and has a highly conserved motif of which the consensus sequence is TYTFTDYVD (SEQ ID NO: 16), wherein the protein is isolated from coagulase-negative Staphylococcus epidermidis (claim 13).

Doucette-Stamm et al teach an isolated polypeptide and nucleic acid sequences derived from Staphylococcus epidermidis (see SEQ ID NO. 5314) that has 100% homology to the instant SEQ ID NO. 16 and 99.9% to the instant SEQ ID NO. 10. Doucette-Stamm et al teach antibodies raised against the polypeptide (see abstract, column 3 lines 15-27, column 9 lines 7-27, STIC Results). Doucette-Stamm et al teach antibodies reactive with S. epidermidis polypeptides. Doucette-Stamm et al teach anti-protein/anti-peptide antisera or monoclonal antibodies can be made by standard protocols. Doucette-Stamm et al teach that the progress of immunization can be monitored by detection of antibody titers in plasma or serum (see column 40 lines 29-64). Therefore Doucette-Stamm et al anticipate an isolated antibody that binds to the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis. Doucette-Stamm et al inherently teach the protein is cell-wall associated, and binds both soluble and immobilized fibrinogen. The antibodies of Doucette-Stamm et al inherently recognizes a protein that is cell wall-associated, exhibits cation-dependent ligand-binding and has a highly conserved motif of which the consensus sequence is TYTFTDYVD (SEQ ID NO: 16). Therefore Doucette-Stamm et al anticipate an isolated antibody raised against the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis, which is raised against the A region of the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis, wherein the SdrG fibrinogen-binding protein comprises SEQ ID NO:10. Doucette-Stamm et al anticipate isolated antisera containing the antibody. Doucette-Stamm et al anticipate an isolated antibody that is reactive with the ligand binding A region of the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis. Doucette-Stamm et al anticipate an isolated antibody reactive with a protein that is cell wall- associated, exhibits cation-dependent ligand-binding and has a highly conserved motif of which the consensus sequence is TYTFTDYVD (SEQ ID NO: 16), wherein the protein is isolated from coagulase-negative Staphylococcus epidermidis, wherein the protein comprises the SdrG fibrinogen-binding protein isolated from coagulase- negative Staphylococcus epidermidis, wherein the protein comprises the ligand binding A region of the SdrG fibrinogen-binding protein isolated from coagulase-negative Staphylococcus

epidermidis (see abstract, column 3 lines 15-27, column 9 lines 7-27, STIC Results, column 40 lines 29-64).

As to dependent claim 9, a diagnostic kit comprising the antibody according to Claim 1 and means for identifying binding by said antibody. As to independent claim 11, a diagnostic kit comprising antibodies reactive with an SdrG protein from coagulase-negative Staphylococcus epidermidis which is cell-wall associated and which binds both soluble and immobilized fibrinogen. As to independent claim 12, a diagnostic kit comprising antibodies reactive with a protein that is cell-wall associated, exhibits cation-dependent ligand-binding and has a highly conserved motif of which the consensus sequence is TYTFTDYVD, wherein the protein is isolated form coagulase-negative Staphylococcus epidermidis. A kit is defined as a set or collection of articles used together therefore Doucette-Stamm et al anticipate a diagnostic kit.

Status of the Claims

9. No claims are allowed.

Claims 1-6 and 8-15 are rejected.

Claim 7 is objected to as being dependent on a rejected base claim.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina A Archie
Examiner
GAU 1645
REM 3B31

MARK NAVARRO
PRIMARY EXAMINER